IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS

CHILDREN'S HEALTH DEFENSE, *et al.,*	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 6:22-cv-00093
	)	
FOOD and DRUG ADMINISTRATION, *et al.*	)	
	)	
Defendants.	)	
_____	)	

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

TO THE HONORABLE JUDGE OF THE COURT:

Plaintiffs Children's Health Defense ("CHD"), Deborah L. Else, and Sacha Dietrich (hereinafter collectively "Plaintiffs"), file this opposition to Defendants U.S. Food and Drug Administration's ("FDA"), Janet Woodcock's and Robert M. Califf's, (hereinafter collectively "Defendants') Motion to Dismiss for Lack of Subject-Matter Jurisdiction and Failure to State a Claim Upon Which Relief Can Be Granted ("Motion") [ECF No. 18].

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INTRODUCTION

Defendants consider themselves to be above the law, claiming (1) no court has authority over them for their actions in this matter; (2) that Congress' plain limits under the APA do not apply to them, and (3) that federal agencies are free to ignore the injuries their actions inflict. The injury here is of the gravest variety, namely a foreseeable, coerced injection of a dangerous and medically unnecessary experimental biologic. Plaintiffs Else and Dietrich experience fear, intimidation and discriminatory treatment as their children refuse this experimental product. Plaintiffs are members of a group that continues to grow as Defendants unlawfully make more and more children eligible for their authorized biologic.

Defendants did not and cannot substantially defend the substance of their actions or dispute the equitable grounds for an administrative stay under the Administrative Procedures Act ("APA"). Hence, Plaintiffs' stay must be granted, and Defendants' motion to dismiss denied.

FACTUAL AND PROCEDURAL BACKGROUND

On October 29, 2021, the FDA granted an emergency use authorization ("EUA") for the Pfizer-BioNTech COVID-19 mRNA biologic for children ages 5-11. In doing so, the FDA willfully ignored the overwhelming data, scientific studies, and case reports indicating not only that the risks of the COVID-19 vaccines to children were significantly higher than the benefits, but also that it was wholly unnecessary to vaccinate children between the ages of 5-11 against COVID. Defendants here are intentionally fast-tracking a biologic via an authorization process reserved for the most emergent and extreme circumstances. The FDA has exceeded the scope of its authority allowed under the emergency use authorization statute. No emergency for children ages 5-11 from COVID-19 existed or exists as healthy children in this age cohort have a

statistically zero risk of death from SARS-CoV-2 infection. By ignoring this fact, FDA has abused its authority.

CHD's prescience in confronting this unauthorized agency action is evidenced in CHD's Citizen Petition filed with the FDA on May 16, 2021. It was based on the FDA's history of illicit behavior regarding COVID-19 vaccines. In it, CHD requested that the FDA refrain from licensing COVID-19 vaccines and revoke EUAs for the three existing COVID vaccines. Compl. ¶ 39. The FDA, by ignoring the evidence raised in the Citizen Petition and over 30,000 comments from interested persons, dismissed CHD's concerns in its reply and continued forward in its spree of authorizations and approvals. VAERS statistics[1] bear out that what CHD feared and warned of has now occurred.

The FDA's decision to grant this EUA took on increasing importance when, as expected, state governments and schools began preparing to or actually mandated COVID-19 vaccines as a prerequisite for children's school attendance. These policies are natural, direct, and foreseeable consequences of Defendants' actions. Federal law incorporating the Nuremberg Code and enshrined informed consent norms have been completely ignored due to FDA's actions. The FDA certainly had reasonable knowledge before authorizing this biologic that childhood vaccine mandates would be implemented, as several states, school districts, and private businesses promised to implement them as soon as the FDA granted the EUA.

Societal consequences for young children who remain unvaccinated against COVID-19 are far more critical to their mental and physical well-being than any danger they'd otherwise face from COVID-19 itself. Discrimination, peer pressure and denial of medical treatment are

[1] 27,532 deaths and 51,163 Permanent Disabilities from COVID-19 vaccines reported to VAERS as of April 29, 2022, available at https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=049432C0E3892D8E407DF2E0614F.

extremely prevalent. The known, negative health impacts of those children who have received the Pfizer-BioNTech COVID-19 vaccines are distressing. The unknown, long-term injuries may be horrific. FDA's chicanery must be called out for what it is: unethical, illegal, and abusive.

STANDARD OF REVIEW

"Federal Rule of Civil Procedure 8(a)(2) requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.' " *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 555 (2007) (citing *Conley v. Gibson,* 355 U.S. 41, 47, 78 S. Ct. 99, 2 L.Ed. 2d 80 (1958)). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. at 570). Furthermore, the allegations of the complaint must be taken as true. *Jenkins v. McKeithen,* 395 U.S. 411, 421-422 (1969). "In passing on a motion to dismiss . . . for failure to state a cause of action, the allegations of the complaint should be construed favorably to the pleader." *Scheuer v. Rhodes,* 416 U.S. 232, 236, 94 S. Ct. 1683, 40 L. Ed. 2d 90 (1974); *see also Bustos v. Martini Club, Inc.,* 599 F.3d 458, 461 (5th Cir. 2010).

ARGUMENT

The FDA is not above the law, the courts, the Constitution, or the citizens whom its actions may injure. The Defendants' argument asks this court to declare itself impotent, the judiciary an empty chamber, the balance of powers permanently imbalanced, and the Constitutional check on executive power just words on paper without effect. That was never the law and is not the law. The court should deny Defendants' motion to dismiss and issue the requested remedial relief pending the remainder of the litigation. Such remedy must be granted

to prevent millions of children from losing their Constitutional rights to informed consent, a right the world once considered so universal and sacred, as a *jus cogens* value, that the U.S. ordered the execution of those who violated it at Nuremberg in 1947. The FDA is not above any law, any court, or any citizen.

The Constitutional question regarding standing is answered since there is a "case or controversy" here. "At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss we "presum[e] that general allegations embrace those specific facts that are necessary to support the claim." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992) (citing *Lujan v. National Wildlife Federation*, 497 U.S. 871, 889, 110 S. Ct. 3177, 111 L.Ed.2d 695 (1990)).

First, the APA expressly authorizes standing for citizens injured by agency action: "a person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. Indeed, the entire purpose of the APA is to assure judicial review of agency action, specifically authorizing federal courts to "hold unlawful and set aside agency action findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority or limitations." 5 U.S.C. § 706(2)(A), (C).

I. Plaintiffs Have Article III Standing

Art. III § 2 of the United States Constitution requires a "case" or "controversy." "The presence of one party with standing is sufficient to satisfy Article III's case-or-controversy requirement." *Rumsfeld v. Forum for Academic & Institutional Rights, Inc.*, 547 U.S. 47, 53, n2 (2006). The Court construes this to mean that a plaintiff has a "personal interest at the

commencement of the litigation." *Barry v. Lyon*, 834 F.3d 706 (2016); see *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992).

An organization can demonstrate standing in two ways: (1) associational standing ("the organization can assert representational standing on behalf of its members") and (2) organizational standing ("an organization may have standing on its own behalf.") *Patterson v. Rawlings*, 287 F. Supp. 3d 632 (N.D. Tex. 2018). CHD clearly satisfies both theories of standing to establish an injury-in-fact and to bring this suit. *See e.g.*, 5 U.S.C. § 701-706; *Bank of Am. Corp. v. City of Miami, Fla.,* 137 S. Ct. 1296, 1303 (2017); *Summers*, 555 U.S. at 494; *see also OCA-Greater Houston v. Texas,* 867 F.3d 604, 610 (5th Cir. 2017) Furthermore, Plaintiffs Deborah L. Else and Sacha Dietrich satisfy Article III standing individually and on behalf of their children.

a. Plaintiff CHD Has Standing

Organizational standing here clearly exists as CHD has Article III standing in its own right (as opposed to suing as a representative of its members) since it is able to allege injury to its organizational activities and a consequent drain on its resources. In *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 378 (1982) ("Havens Realty"), the Supreme Court held that an organization's pleading sufficiently meets Article III standing where it alleges that a "concrete and demonstrable injury to the organization's activities – with the consequent drain on the organization's resources - …" "Ultimately, to establish standing in its own right, an organization must allege facts to show that it devoted resources to counteract defendant's alleged unlawful practices." *Advocacy Ctr. V. La. Tech Univ.*, 2019 U.S. Dist. Lexis 47726 *8 (quoting *Association of Community Orgs. For Reform Now v. Fowler*, 178 F.3d 350, 360 (5th Cir. 1999) [an organization has standing to sue on its own behalf where it devotes resources to counteract a

defendant's allegedly unlawful practices. *See* 455 U.S. at 379; *Spann*, 899 F.2d at 28; *Cleburne Living Ctr., Inc. v. City of Cleburne*, 726 F.2d 191, 202-03 (5th Cir. 1984), affirmed in part and vacated in part on other grounds, 473 U.S. 432 (1985)]. In *El Rescate Legal Services, Inc. v. Executive Office of Immigration Review*, 959 F.2d 742, 748 (9th Cir. 1991), the Ninth Circuit held:

> "[T]he organizations involved in the present case were established to assist Central American refugee clients, … in their efforts to obtain asylum and withholding of deportation in immigration court proceedings. The allegation that the [defendant government agency]'s policy frustrates these goals and requires the organizations to expend resources in representing clients they otherwise would spend in other ways is enough to establish standing." (citing *Havens Realty*, *supra*, 455 U.S. at 379.)

The expenses associated with litigation that a plaintiff organization is required to expend in pursuing a lawsuit are a drain on organizational resources sufficient to establish the organization's standing in its own right.

Decisions of other Circuit Courts affirm this same principle of an organization's standing in its own right under Article III, where its pre-litigation efforts to evaluate and challenge government acts results in a drain on the organization's resources. For example, in *Hooker v. Weathers*, 990 F.2d 913, 915 (6th Cir. 1993) ("Hooker"), the Sixth Circuit found standing in its own right as to an organizational plaintiff, the Fair Housing Contact Service, which was an organization that worked to eliminate discriminatory housing practices, finding the organization devoted resources to investigating the defendant trailer park's practices and alleged in its pleading that it had confirmed that the defendants discriminate on the basis of familial status. *Ibid*.

Here, the allegations in the Complaint sufficiently pleaded that Plaintiff CHD had organizational standing in its own right under Article III. First, on May 16, 2021, CHD filed a 19-page Citizen Petition with the FDA, requesting it to refrain from licensing COVID-19

vaccines and to revoke EUAs for the three existing vaccines. Compl. ¶ 39. CHD's Citizen Petition was the result of countless hours of work and effort by CHD personnel, including but not limited to Meryl Nass, M.D. (Scientific Advisory Board member) and Robert F. Kennedy, Jr. (Board Chair and Chief Litigation Counsel), requesting that the FDA revoke the EUA for existing COVID-19 vaccines and refrain from approving and licensing them. *Id.* Additionally, the Citizen Petition assembled and brought to the FDA's attention a tremendous amount of detailed factual findings and research regarding the risks to public health and safety, effectiveness of vaccines (or rather lack thereof), the FDA's misbranding of the vaccine authorizations, and the serious injuries and consequences spawned by the FDA's actions to CHD members and their children.

As such, CHD has Article III standing in its own right because it was required to expend a tremendous amount of manpower and work hours just to put together its Citizen Petition dated May 16, 2021 alone. In addition, CHD was required to expend even more time, manpower and expense in reviewing the FDA's 52-page denial response, consult with the CHD's members, experts and legal counsel, follow and aggregate the massive amount of scientific research regarding the consequences following the administration of the vaccine to individuals five years of age and up, and then file the underlying civil action requesting the courts step in to review the integrity of the FDA's procedures under the APA.

CHD has diverted and continues to divert substantial resources, time, and manpower from its current activities due to the threat that the FDA's authorization poses to millions of children, a risk that CHD has been predicting and warning about for months. Such resource diversion is, in itself, grounds for standing. *Bank of Am. Corp. v. City of Miami, Fla.,* 137 S. Ct.

1296, 1303 (2017). This substantial drain on CHD's resources directly and proximately caused by FDA's actions alone, confers Article III standing to CHD in its own right.

Finally, Supreme Court precedent holds that where a plaintiff sufficiently alleges actual injury to itself under certain federal statutes, the plaintiff is permitted to prove that the rights of others were also so infringed and to seek relief on their behalf as well. Thus, in *Gladstone*, *supra*, 441 U.S. at 103, a municipality sued a real estate broker for violating the Civil Rights Act by steering prospective home buyers to different residential areas according to race. Because the city itself claimed actual injury (loss of racial balance and stability), it had standing to prove that the rights of others (prospective home buyers) were also infringed. *See also Virginia v. American Booksellers Ass'n, Inc*., 484 U.S. 383, 392-393 (1988).

Plaintiff CHD also has associational standing to bring this suit. " 'Associational standing' is derivative of the standing of an association's members, requiring that they have standing and that the interests the association seeks to protect be germane to its purpose." *OCA-Greater Houston,* 867 F.3d at 610. "An organization has standing to bring suit on behalf of its members when: (1) its members would otherwise have standing to sue in their own right; (2) the interests it seeks to protect are germane to the organization's purpose; and (3) neither the claim asserted nor the relief requested requires the participation of individual members." *Texans United for a Safe Econ. Educ. Fund v. Crown Cent. Petroleum Corp.*, 207 F.3d 789, 792 (5th Cir. 2000) (citing *Hunt v. Wash. State Apple Adver. Comm'n,* 432 U.S. 333, 343, 97 S.Ct. 2434, 53 L.Ed.2d 383 (1977); *Friends of the Earth, Inc. v. Chevron Chem. Co.,* 129 F.3d 826, 827–28 (5th Cir. 1997)). Indeed, it is "common ground that…organizations can assert the standing of their members." *Summers*, 555 U.S. at 494.

i. *CHD has Identified Members Who Have Standing to Sue In Their Own Right*

To satisfy this first element: "It generally suffices for an association to demonstrate 'at least one of [its] members would have standing to sue on his own.'" *Waskul v. Washtenaw Cty. Cmty. Mental Health*, 900 F.3d 250 (6th Cir. 2018) (quoting *Lewis v. Casey*, 518 U.S. 343, 358 n.6, 116 S. Ct. 2174, 135 L.Ed. 2d 606 (1996)). Therefore, the organization must "show that one of its named members '(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.'" *Waskul*, 900 F.3d at 255 (quoting *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547, 194 L. Ed. 2d 635 (2016)). "If in a proper case the association seeks a declaration, injunction, or some other form of prospective relief, it can reasonably be supposed that the remedy, if granted, will inure to the benefit of those members of the association actually injured." *Warth v. Seldin*, 422 U.S. 490, 515, 95 S. Ct. 2197, 45 L. Ed. 2d 343 (1975).

Defendants argue that CHD does not satisfy the first factor. Motion to Dismiss at 10. However, CHD's allegations satisfy associational standing because Deborah L. Else and Sacha Dietrich, both members of CHD, have been injured by FDA's action and have individual standing. Thus, CHD has associational standing to bring suit on their behalf.

Many of CHD's members would have standing to sue in their own right because FDA's EUA injured all parents who have young children now threatened by the authorization at issue. Plaintiffs Deborah L. Else and Sacha Dietrich chronicle imminent and irreparable harm associated with coercion of children to take this dangerous biologic and encroaching mandates that have resulted from FDA's authorization.

Because of FDA's misrepresentation that the COVID-19 vaccine is beneficial to children, Plaintiffs and their children experience pressure, coercion, and discrimination to have the

children take the vaccine. Plaintiff Deborah Else attests to enduring vaccine propaganda from school administrators and pediatricians aimed at her children. Compl. ¶ 52; Else Decl., ECF No. 14-1. Plaintiff Sacha Dietrich further asserts that her children experience constant harassment from directives and pressure to receive the COVID-19 biologic from the media and other children. Compl. ¶ 53; Dietrich Decl., ECF No 14-1. Plaintiffs' children are subjected to an inundation of pro-vaccine messaging via advertisements on television, radio shows, announcements, and signage in stores and even promotion in children's television programming. The looming threat of being pushed out of society faces Plaintiffs' children as the culture of mass vaccination and medical mandates, now directed at children ages five through eleven, perpetuates as a result of FDA's actions. Injunctive relief that would stay the FDA's five through eleven EUA and prevent any further marketing or promotion of the biologic to children would alleviate this harm facing Plaintiffs and countless other CHD members.

Because both Deborah L. Else and Sacha Dietrich individually satisfy the requirements of Article III standing, CHD has identified members who have standing to sue in their own right. *Spokeo, Inc. v. Robins*, 136 S. Ct. at 1547.

ii. *CHD Aims to Protect Interests Germane to Its Purpose*

Defendants do not contest that CHD clearly satisfies the other two criteria for associational standing. Plaintiff CHD is a large organization that has millions of people associated with it and continues to grow. While their members boast tens of thousands, CHD reaches in the millions every month through their publications, TV channels and social media. CHD provides that its mission is to "end childhood health epidemics by working aggressively to eliminate harmful exposures, hold those responsible accountable, and to establish safeguards to

prevent future harm."[2] The organization goes on to state in its purpose statement that "the one thing we all share is our passionate belief that we have public health policies and practices that are harming our children. For the future good health of our children and planet, we call for more research and transparency."3 These goals pertain not only to actions that directly affect children, but also those that will set long-lasting and dangerous precedents that will undoubtedly affect future generations of youth. CHD is the voice for those oppressed by corporate capture of federal agencies, as we have here.

The FDA's EUA for children ages 5-11 affects CHD's members and their children. The current and imminent impact on children could hardly be more serious.

iii. ***The Relief Sought by CHD Does Not Require the Participation of Individual Members***

Finally, as the FDA does not contest in their motion, CHD's claims do not require any individual members to participate directly in the suit and thus the third factor of associational standing is satisfied.

In *Associated Contractors of America v. Metropolitan Water Dist. Of S. Cal*., 159 F.3d 1178, 1181 (9th Cir. 1998), the court held that the individual participation of an association of contractors was not required to assert standing, where declaratory and injunctive relief were sought rather than monetary damages, and thus individualized proof was not necessary to resolution of the action. Similarly, Plaintiffs' Complaint contains no prayer for monetary damages, only for the court to stay and vacate the FDA's actions regarding the COVID vaccines at issue in the action. Compl. Prayer for Relief. As such, individual participation by members that are part of the CHD's organization is not required.

[2] https://childrenshealthdefense.org

CHD has standing to sue for injuries caused by Defendants to others for the same conduct it imposes upon Plaintiffs Deborah L. Else and Sacha Dietrich, who submitted declarations in support of Plaintiffs' Motion to Stay.

b. Plaintiffs Deborah L. Else and Sacha Dietrich Have Standing as Individuals

"To satisfy Article III's standing requirements, a plaintiff must show (1) it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 181, 120 S. Ct. 693, 145 L.Ed. 2d 610 (2000) (quoting *Lujan*, 504 U.S. at 560-561). "It can scarcely be doubted that for a plaintiff who is injured or faces the threat of future injury due to illegal conduct ongoing at the time of suit, a sanction that effectively abates that conduct and prevents its recurrence provides a form of redress." *Laidlaw*, 528 U.S. at 185-86.

Defendants incorrectly allege that Plaintiffs Deborah L. Else and Sacha Dietrich lack standing and therefore fail to establish this Court's subject-matter jurisdiction. Motion to Dismiss at 6. Plaintiffs Deborah L. Else and Sacha Dietrich have shown that they have suffered an injury in fact, that is (a) concrete and particularized, and (b) actual or imminent, the injury being fairly traceable to the FDA's actions, and injunctive relief will redress their injuries, which satisfies Article III's case-or-controversy requirement. *Lujan* 504 U.S. at 560-561.

Plaintiffs' children have been subjected to continuous advertisements, pressure, and coercive tactics to induce them to take the EUA COVID-19 vaccine. Their children face the risk of expanding vaccine mandates, including those preventing them from receiving life-saving transplants and medical treatment. Defendants' note that Texas Governor Greg Abbott has

signed an executive order prohibiting vaccine mandates. Motion to Dismiss at 8. However, such an executive order has not prevented discriminatory and cruel treatment towards the unvaccinated –particularly children—which, as Defendants admit, is in direct violation of the assurance included in the EUA statute that a decision to not take the COVID-19 vaccine "will not change [the] child's standard medical care." Motion to Dismiss at 4; *see* 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III).

The threat of being denied life-saving treatment is not a remote risk, as Defendants suggest. Motion to Dismiss at 7. No child is immune from the constant risk of an accidental injury or emergency medical condition. Defendants hope to evade responsibility by claiming that because Plaintiffs' children have fortunately not yet suffered an emergency health situation and required life-saving treatment, Defendants do not put them at any such risk. Furthermore, Defendants would have the Court believe that coercive pressures and propaganda aimed at young children to take a dangerous, experimental, mRNA gene therapy do not alone present an injury. In fact, they do. Indeed, in granting a preliminary injunction prohibiting the enforcement of the Minor Consent for Vaccinations Act Amendment of 2020 (which allowed a minor as young as 11 years old to consent to receiving a vaccine), the D.C. District Court held that there was imminent injury when a young 13-year-old child felt "singled out for being unvaccinated against COVID-19" and experienced substantial pressure to take the vaccine. Order Granting Plaintiffs' Motion for Preliminary Injunction at 8-12, *Booth et al v. Bowser et al,* (No. 1:21-cv-01857-TNM).

Furthermore, Defendants allege that "any injury deriving from the independently developed messages of third parties, such as schools, pediatricians, or stores, cannot be fairly traced to FDA." Motion to Dismiss 9. However, FDA was aware of both government and

privately implemented vaccine mandates for individuals of all age cohorts who were eligible to receive a vaccine. FDA also had reasonable knowledge that entities were preparing to implement mandates as a direct result of FDA's EUA. Without FDA's action at issue here, none of the presented injury would have occurred, and Plaintiffs would not be under current threat.

This injury, outlined in detail in Plaintiffs' declarations filed along with their Motion to Stay, is both concrete and particularized, and actual or imminent. The injury Plaintiffs and their children sustained stems directly from FDA's illicit authorization and the false representation that this biologic is a "vaccine" that has been adequately tested for safety and confers benefit to children.

The relief sought by Plaintiffs will immediately cure this injury and protect not only Plaintiffs and their children, but all current and future children between the ages of 5-11 from FDA's arbitrary and capricious action.

II. Sovereign Immunity Does Not Prevent this Challenge

Defendants incorrectly argue that the FDA here enjoys sovereign immunity and Plaintiffs' causes of action are beyond the APA's scope of review. Motion to Dismiss at 12.

A waiver of sovereign immunity is "unequivocally expressed" in the APA. *Lane v. Pena*, 518 U.S. 187, 192, 116 S.Ct. 2092, 135 L.Ed.2d 486 (1996). 5 U.S.C. § 702 presents two requirements for establishing a waiver of sovereign immunity: (1) the plaintiff must "identify some 'agency action' affecting him in a specific way, which is the basis of his entitlement for judicial review," *Alabama-Coushatta Tribe of Texas v. United States*, 757 F.3d 484 (5th Cir. 2014) (quoting 5 U.S.C. § 702), and (2) the plaintiff must demonstrate that she has "suffered legal wrong because of the challenged agency action, or is adversely affected or aggrieved by that action within the meaning of a relevant statute." *Lujan,* 497 U.S. at 883. "In such

circumstances, where the Plaintiff is not seeking money damages, the APA acts as a waiver of the government's sovereign immunity, allowing the plaintiff to proceed in federal court to rectify agency action." *Valerio v. Limon*, 533 F. Supp. 3d 439, 450 (S.D. Tex. 2021).

Plaintiffs clearly meet these criteria. Defendants incorrectly argue that their conduct is somehow beyond the scope of APA accountability. Defendants claim *Ass'n of Am. Physicians & Surgeons v. United States FDA* ("AAPS I") as precedent to support Defendants' argument that its arbitrary and capricious conduct are exempt from review under the APA because FDA's action under 21 U.S.C. § 360bbb-3 is subject to agency discretion. *Ass'n of Am. Physicians & Surgeons v. United States FDA*, No. 20-1784, 2020 U.S. App. LEXIS 30622 (6th Cir. Sep. 24, 2020). That case, still under appellate review, stands for no such proposition.

Exemptions from judicial review are rare and "not generally to be 'liberally construed.'" *United States v. Nordic Vill. Inc.*, 503 U.S. 30, 34, 112 S. Ct. 1011, 117 L. Ed. 2d 181 (1992). There is a "'strong presumption' that Congress intends that the federal courts review agency action." *Lundeen v. Mineta*, 291 F.3d 300, 305 (5th Cir. 2002). Although 21 U.S.C. § 360bbb-3 does give discretion to the Agency and the Secretary of Health and Human Services, this discretion is not without bounds. The 5 U.S.C. § 701(a)(2) exception to sovereign immunity for action delegated to agency discretion is read "quite narrowly, restricting it to 'those rare circumstances where the relevant statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion.' " *Weyerhaeuser Co. v. United States Fish and Wildlife Serv.*, 139 S.Ct. 361, 370, 202 L.Ed.2d 269 (2018) (quoting *Lincoln v. Vigil*, 508 U.S. 182, 191, 113 S.Ct. 2024, 124 L.Ed.2d 101 (1993)). FDA authorizations and approvals are not actions that are "traditionally committed to agency discretion." *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2568, 204 L. Ed. 2d 978 (2019).

In any event, "nothing in the subsequent enactment of the APA altered the [pre-existing] doctrine of review." *Chamber of Commerce of the United States v. Reich*, 74 F.3d 1322, 1328 (D.C. Cir. 1996); see *Duncan v. Muzyn*, 833 F.3d 567, 578 (6th Cir. 2016) (recognizing the ongoing vitality of pre-APA review). As Prof. Davis put it shortly after the APA's enactment, when review is cut off under the Act (i.e., the APA), "[t]he result is that the pre-Act law continues." Kenneth Culp Davis, Nonreviewable Administrative Action, 96 U. PA. L.REV. 749, 776 (1948). Under that pre-APA review, "if an official acts solely on grounds which misapprehend the legal rights of the parties, an otherwise unreviewable discretion may become subject to correction." *Arenas v. United States*, 322 U.S. 419, 432 (1944).

The FDA, acting as a government agency, cannot evade responsibility for arbitrary and capricious actions under the APA, especially considering the perilous nature of authorizing biologics that skip traditional safety protocols. Holding that the FDA is immune from accountability here would deny citizens any proper recourse for addressing Defendants' unlawful operations.

III. Plaintiffs State Cognizable Claims on Which This Court Can Grant Relief

The FDA does not have unlimited authority to release minimally tested and risk-heavy medical products even in the most emergent of circumstances, particularly for children. The FDA took the unprecedented step to authorize a biologic that is not a traditional "vaccine," and is neither safe nor effective for young children, who are least at risk from COVID-19. In doing so, the FDA has created the illusion of safety and a false guarantee that this product confers some level of protection. The FDA has actively deceived the public to the detriment of millions of children and their families. This is reason sufficient to grant the stay.

CHD has sufficiently detailed the FDA's wrongdoing. Plaintiffs gave fair notice of the claim and sufficiently cited 5 U.S.C. § 701(2)(A), showing entitlement to relief for a single cause of action with facts and verified, exhibit-supported harm. Not only are the facts true, but they must also be accepted as true – something Defendants refuse to acknowledge.

a. Plaintiffs' Challenge to the EUA is Reviewable

The APA expressly authorizes standing for citizens who are harmed by an agency's unlawful activity: "a person suffering legal wrong because of agency action…is entitled to judicial review thereof." 5 U.S.C. § 702. Indeed, the entire point of the APA was to assure judicial review of agency action, specifically authorizing federal courts to "hold unlawful and set aside agency action . . . found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; contrary to constitutional right, power, privilege, or immunity; [or] in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A)-(C).

b. Plaintiffs Successfully Allege that Defendants Violated the APA

The APA affords Plaintiffs the right to challenge Defendants' conduct. It is important for the Court to be aware of the scope of review it has when examining an administrative exercise of discretion. The Supreme Court has indicated that a two-step procedure is required, entailing first, a determination whether the agency has acted within the scope of its statutory authority, and second, whether the actual choice made was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971).

i. FDA's Arbitrary and Capricious Authorization

To make a finding of "arbitrary" and "capricious" agency action, the Court must undertake a "searching and careful" inquiry into the facts. *Id.* An agency's action is "arbitrary

and capricious" if it did not articulate any rational connection between the facts it found and the choices it made. *Burlington Truck Lines v. United States*, 371 U.S. 156, 168, 83 S. Ct. 239, 9 L.Ed.2d 207 (1962).

Plaintiffs successfully pleaded that the FDA's EUA for children ages 5-11 fails to meet this standard. In its approval, the FDA:

1. failed to examine relevant data;

2. failed to articulate its standard for assessing the issue at hand;

3. relied on factors not intended for it to consider;

4. failed to consider an important aspect of the problem;

5. offered an explanation that runs counter to the evidence; or

6. failed any aspect of reasoned decision-making in the process it utilized to come to its conclusions.

Defendants authorized Pfizer-BioNTech's EUA for children ages 5-11 despite the abundance of evidence indicating that the biologic poses a serious risk to young children and the overwhelming lack of success of the administration of the same vaccines to individuals ages 12 and up. The FDA turned a blind eye to the reports of serious adverse effects, deaths and warnings of severe long-term effects that have yet to be investigated. The FDA cannot hand-pick which facts to utilize in its determination and which to ignore; it has a duty to examine the totality of the evidence – a duty it has failed. The FDA granted this EUA knowing that the EUA vaccine is liability-free, manufactured without good manufacturing practices required for licensed products, and that the product would be mandated for some young children. The FDA has capitulated to pharmaceutical and executive branch agendas, while disregarding the agency's

purpose. Politics and industry pressure should play no role in the authorization process, yet they obviously appear to have been central in the FDA's decision-making process here.

Defendants acted arbitrarily and capriciously by failing to engage in a pluralistic, critical, open, transparent and scientific dialogue with the public and medical community based on careful, deliberative evaluation of all relevant research before rushing the authorization of this vaccine. FDA's EUA for children ages 5-11 violated the requirement of reasoned decision-making detailing all the areas under 5 U.S.C. § 701 that were not followed. Unlike rational-basis review, review of agency action is based on the record before the agency. Compare *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto Ins. Co.*, 463 U.S. 29, 50 (1983) (APA); *SEC v. Chenery Corp.*, 318 U.S. 80, 88 (1943) (pre-APA) with F.*C.C. v. Beach Commc'ns, Inc.*, 508 U.S. 307, 315 (1993). The APA's requirement of "reasoned decision making" is offended since the FDA "agency action is lawful only if it rests 'on a consideration of the relevant factors.'" *Michigan v. E.P.A.*, 576 U.S. 743, 750 (2015) (citation omitted). As a result, Defendants' actions warrant vacatur and remand.

Furthermore, CHD successfully pleads Defendant FDA exceeded its statutory authority when authorizing the EUA for children ages 5-11. "The reviewing court must also hold unlawful and set aside agency action that is contrary to constitutional right, in excess of statutory authority, or without observance of procedure required by law." *Monumental Task Comm., Inc. v. Foxx*, 157 F. Supp. 3d 573 (E.D. La. 2016), *aff'd sub nom. Monumental Task Comm., Inc. v. Chao*, 678 F. App'x 250 (5th Cir. 2017) (citing 5 U.S.C. § 706(2)(B)-(D)). The FDA does not contest the conclusion that SARS-CoV-2 poses no "actual" or "potential" emergency for children in this age cohort and therefore its action was not allowed under the emergency use statute. 21

U.S.C. § 360bbb-3(a)(1). In several respects, FDA's actions exceeded Defendants' statutory authority, which is reviewable under both the APA and pre-APA review.

CONCLUSION

Plaintiffs ask for this Court to vacate and remand the FDA's decision to grant the EUA for Pfizer-BioNTech's COVID-19 vaccine for children 5-11 on the grounds that FDA's action violated the APA, 5 U.S.C. § 706(2)(A), was arbitrary and capricious, and exceeded the agency's statutory authority. For the foregoing reasons, this Court should deny Defendants' Motion to Dismiss and grant Plaintiffs' motion to stay.

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Respectfully submitted,

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